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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/249,003	02/12/99	WILSON	P 8416ZYX

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EXAMINER	
MONSHIPOURI, M	
ART UNIT	**PAPER NUMBER**
1652	6

DATE MAILED: 01/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/249,003	Wilson et al.
Examiner	**Group Art Unit**
Maryam Monshipouri	1652

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-31* is/are pending in the applicat

Of the above, claim(s) *7-10, 13-15, and 27-31* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-6, 11, 12, and 16-26* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Applicant's response dated 10/26/99 (paper #5) in which Group I invention was elected for continued prosecution is acknowledged.

Claims 1-6, 11-12, and 16-26 are under examination on the merits. Claims 7-10, 13-15, and 27-31 are withdrawn from further examination as drawn to non-elected invention.

Claim Objections

1. Claim 1 is objected to because of the following informalities: The term " or or fragment thereof" in claim 1 does not make sense. Applicant is advised to replace this term with " or a fragment thereof" as it is presumed that applicant is claiming more than one fragment. Appropriate correction is required.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-6, 11-12 and 16-26 are rejected under the judicially created doctrine of double patenting over claims 1-29 of U. S. Patent No. 5,932,211 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Claims 1-6, 11-12 and 16-26 of instant application are directed to a recombinant human Iduronate 2-sulfatase (IDS) retaining enzymatic activity wherein said recombinant IDS produced in Chinese Hamster Ovary (CHO) cells and is more highly glycosylated than the naturally occurring enzyme, as well as pharmaceutical compositions comprising said recombinant IDS, useful for treating patients suffering from deficiency in IDS. The claimed subject matter instantly is within the scope of claims 1-29 of U.S. Patent No. 5,932,211 which are directed the same recombinant enzyme expressed in eukaryotic cell (which encompasses CHO cells) with the same molecular weight as well as pharmaceutical compositions comprising said recombinant enzymes.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-6, 11-12 and 16-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for recombinant IDS expressed in CHO cells and pharmaceutical compositions comprising said enzymes, does not reasonably provide enablement for its fragments retaining enzymatic activity and pharmaceutical compositions comprising said fragments.

The criteria for determining undue experimentation, summarized in *re wands*, 8 USPQ2nd 1400 (Fed. Cir. 1988), are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims. The specification defines the term "more highly glycosylated than the naturally occurring enzyme" in page 5 of the specification. According to this definition a more highly glycosylated IDS of the present invention has a molecular weight of at least 5KD greater than the naturally occurring enzyme. The specification however, does not define the term "more highly glycosylated" for fragments which retain enzymatic activity. In other words it is not clear what should the molecular weight of such glycosylated fragments be and by what extent they should be greater than their less/non-glycosylated naturally occurring counterparts. Furthermore, the specification neither provides any

examples of such glycosylated fragments nor teaches how to purify these glycosylated fragments. Considering that a longer fragment with less glycosylated residues is likely to appear as the same molecular weight of a shorter fragment with more glycosylated residues it is not clear how the more glycosylated IDS fragments should be identified, resolved and purified. Current state of prior art does not allow resolving such population of recombinant IDS fragments merely based on their molecular weights. Therefore, due to lack of sufficient teachings and examples in the specification and lack of prior art teachings with regards to preparing such glycosylated fragments the skilled artisan needs to go through the burden of undue experimentation in order to identify, resolve and purify enzymatically active fragments of recombinant IDS and the claimed subject matter goes beyond the scope of the specification. Since the recombinant IDS fragments are not enabled, pharmaceutical compositions comprising said fragments are not enabled either.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "SEQ ID NO:1" in claims 5-6 is indefinite. SEQ ID NO:1 in the sequence listing and the specification is referred to a nucleic acid sequence. However, applicant in claims 5-6 defines the structure of recombinant IDS in terms of SEQ ID NO:1. It is not clear how an

enzyme may have a nucleic acid sequence. Applicant is advised to replace this term by "SEQ ID NO:2" which is an amino acid sequence.

Applicant's arguments with regards to traversal of restriction requirement and rejoining claims 27-31 currently in Group III invention with elected claims 1-6, 11-12 and 16-26 of Group I invention were considered but were not persuasive. Applicant argues that host cells expressing IDS must be properly joined together with said enzyme and pharmaceutical composition comprising said enzyme. The examiner of record would like to point out that host cells expressing the enzyme have entirely different chemical structure and function than the enzyme and belong to class 435 subclass 320.1 which is entirely different than enzyme and pharmaceutical composition classes and subclasses which are 435/196 and 424/94.6, respectively. Therefore, rejoining claims 27-31 to instantly elected claims of Group I invention would impose an undue burden of searching on the examiner. Restriction is maintained according to previous office action (paper #4) and is hereby made FINAL.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308- 1083.

The Examiner can normally be reached daily from 8:30 A.M. to 5:00 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Maryam Monshipouri, Ph.D.

Patent Examiner

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SUPERVISORY PATENT EXAMINER
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